

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW HAMPSHIRE

PAMELA LANGLOIS,

PLAINTIFF

vs.

LINDEN CARE, LLC,

ROCHESTER DRUG CO-OPERATIVE, INC.,

DEFENDANTS

Case No. 1:19-CV-00722

COMPLAINT

Jury Trial Demanded

NOW COMES the Plaintiff, Pamela Langlois, by and through her attorneys, Coughlin, Rainboth, Murphy & Lown, P.A., and complains against the Defendants, Linden Care, LLC, and Rochester Drug Co-Operative, Inc., and alleges the following:

PARTIES

1. The Plaintiff, Pamela Langlois, is an individual with a principal residence located at 7 Kerry Drive, Newton, New Hampshire 03589.

2. Defendant Linden Care, LLC, (hereinafter “Linden Care”) at all times relevant to this Complaint was a limited liability company operating as a concierge pharmacy with a principal place of business and corporate headquarters located at 130 Crossways Park Drive, Suite 101, Woodbury, N.Y.

3. Defendant Rochester Drug Co-Operative, Inc. (hereinafter “RDC”) is a regional wholesale drug cooperative headquartered at 50 Jetview Dr, Rochester, NY 14624.

GENERAL ALLEGATIONS

4. In 2013 Pamela Langlois was a patient at the PainCare clinic in Somersworth, New Hampshire, (hereinafter “PainCare”) being treated for osteoarthritic pain.

5. At PainCare, the Plaintiff came under the care of Physician Assistant, Christopher Clough.

6. Mr. Clough performed multiple injection procedures and provided prescriptions of several opioid medications including Oxycodone to treat the Plaintiff’s pain.

7. On or about, July 29, 2013 the Plaintiff went to PainCare for her normal monthly visit. Without the Plaintiff’s knowledge or agreement, Clough wrote a prescription for a new fentanyl medication called Subsys.

8. Subsys (fentanyl spray) is a sublingual spray which is an opioid pain medication classified as a schedule II substance which is much more potent than morphine and heroin.

9. In January 2012, the FDA had approved Subsys for the management of breakthrough cancer pain in patients 18 years of age and older who are already receiving and are tolerant of opioid therapy for their underlying cancer pain. At no time during her treatment did Ms. Langlois have cancer.

10. Subsys is subject to an FDA-required program known as “TIRF REMS” which imposes rigorous controls on the prescribing and dispensing of medications which pose a risk of misuse, addiction and overdose. The FDA mandates by law an initial dosage of no more than 100 mcg; Ms. Langlois was given an initial dose of 400 mcg.

11. Within a few days of the visit in July 2013, Ms. Langlois received her first shipment of a box of Subsys which was delivered by Fed Ex from the Defendant, Linden Care, a concierge pharmacy in New York.

12. On the day before receiving this first shipment, Linden Care called the Plaintiff to ask her if someone 18 or older would be home to sign for a medication delivery. Ms. Langlois asked what the medication was as she had not been told that Clough had prescribed her a new opioid medication. Mr. Clough had not discussed or made any mention of this new medication with Ms. Langlois during her visit with him on July 29, 2013, the day prior.

13. The Plaintiff was never shown, nor did she sign a TIRF-REMS enrollment form. Ms. Langlois's name is typed into this form in place of the necessary signature, and the form is dated August 8, 2013, several days after the Plaintiff had already received her first prescription of Subsys.

14. At the same time, Mr. Clough was also prescribing other opioid medications for the Plaintiff, including Exalgo and Roxicodone.

15. Mr. Clough wrote in his notes that he was prescribing Subsys as replacement for the Roxicodone, and that the Roxicodone would be discontinued. Ms. Langlois continued to receive a prescription for Roxicodone for the duration of the time she was proscribed Subsys.

16. By November of 2013, Clough had increased the Plaintiff's prescription of Subsys to 1200mcg. The next month it was increased again to 1600 mcg. During this time Ms. Langlois continued to receive Roxicodone.

17. Mr. Clough increased the prescribed dose of Subsys for Ms. Langlois without medical justification until she was on the maximum dosage of 1600 mcg every 4 - 6 hours. Subsys is not meant to be taken in this manner and is only intended to be used as needed when a patient experiences "breakthrough pain."

18. Ms. Langlois became highly dependent on Subsys. On several occasions she lost consciousness due to the effects of Subsys and had to be revived by her husband who thought she had stopped breathing. She became nearly comatose on many occasions and was often in a

“zombie” like state. On one particular occasion Ms. Langlois’s husband nearly called 911, because his wife’s breathing became very shallow and he could not get the Plaintiff to “wake up.”

19. In July of 2014, Mr. Clough abruptly cut Ms. Langlois’s prescription of Subsys in half, dropping her to 800 mcg for the month of August. By October 2014, Mr. Clough cut Ms. Langlois off of Subsys completely without discussing this change in medication with her.

20. On October 23, 2014, Ms. Perry called Mr. Clough’s office to inquire about her Subsys prescription when the drug was not delivered for that month. In the note from this call, Pamela March, Mr. Clough’s assistant, writes “have you discussed discontinuing [Subsys] with her? If so she does not seem to be aware”. Mr. Clough responded only with the words “hold Subsys.”

21. Ms. Langlois experienced serious withdrawal symptoms as Mr. Clough cut in half and then abruptly discontinued her Subsys medication. Ms. Langlois experienced diarrhea, cramping, cold sweats, significant increases in pain, depression and suicidal ideations.

22. Upon information and belief, Mr. Clough’s license was under investigation in the latter part of 2014. His license was later suspended by the New Hampshire Board of Medicine in 2015 and was revoked in 2016. Mr. Clough did not share with Ms. Langlois the real reason that his medical practice was ending. This caused Ms. Langlois to be ignorant of Mr. Clough’s unethical, reckless and careless behavior which had caused the injuries inflicted upon her by Clough and the Defendants.

23. Upon information and belief, Mr. Clough also told the Plaintiff that the practice would no longer be prescribing Subsys because drug addicts had found a way to mix Subsys with caffeine, in order to make the Plaintiff ignorant of the real reason that Subsys was no longer being prescribed. Upon information and belief, this statement by Clough was untrue.

24. Recently, the New Hampshire Attorney General's office began an investigation of Mr. Clough's business dealings with Insys, the manufacturer of Subsys.

25. During this investigation, the Attorney General's office learned that patients in New Hampshire received more than 800 prescriptions and more than 100,000 units of Subsys in 2013 and 2014. During the Attorney General's investigation, it was determined that 84% of the Subsys prescriptions in New Hampshire were written by Physician Assistant Christopher Clough in 2013 and 2014 while he was employed at PainCare in Somersworth.

26. Upon information and belief, an Insys sales representative, Natalie Levine, recruited Mr. Clough to become a speaker for Insys. Ms. Levine also attended "Speaker Bureau" events at high-end restaurants in Portsmouth, NH and Boston, MA. At these events, the Insys sales representative participated in forging the names of supposed attendees at several of these events who were not in fact in attendance at the restaurant. Many of these events were only attended by Clough and Levine and included no actual presentation.

27. Upon information and belief, an Insys sales representative also ordered and/or paid for more dinners at these restaurant events than were for people actually in attendance at the speaking event to make it look as if more people were at the event.

28. The Attorney General's office discovered that Mr. Clough spoke at 39 programs between August 8, 2013 and October 16, 2014. Mr. Clough was paid approximately \$44,000 to "speak" at these sham events.

29. Mr. Clough became a frequent speaker with the Insys Speaker Bureau. A former Insys District Sales Manager, who was recently arrested on federal anti-kickback charges described Clough in an email as a "crucial part of [Insys] Speakers Bureau."

30. Between August 8, 2013 and November 2014 Mr. Clough became one of the highest prescribers of Subsys in the country and the highest prescriber in New Hampshire. Upon

information and belief, Mr. Clough made efforts to prescribe Subsys to approximately 150 patients.

31. To facilitate Clough's prescription of Subsys, Insys pre-populated "OPT IN" forms and TIRF-REMS documents to mislead insurance companies into paying for Subsys.

32. Insys interfered with the doctor/patient relationship by encouraging its salespersons to remove confidential medical records from Clough's office for the purpose of deceiving the plaintiff's health insurance carrier to pay for Subsys.

33. Upon information and belief, employees of Insys fraudulently misrepresented to the Plaintiff's medical insurer the medical condition of Ms. Langlois in order to obtain insurance coverage for Subsys.

34. Insys set up a call center where Insys employees would call insurance companies pretending to be from the office of a treating physician. During these calls they would mislead the insurance company into believing that the conditions of the insured were serious, often misrepresenting a patient's diagnosis and saying that a patient had cancer or dysphasia (difficulty swallowing) in order to make sure that prescriptions for Subsys would be approved.

35. Upon information and belief Insys also provided Clough with a template letter to send to insurance companies in order to get Subsys prescriptions approved. With this template Clough frequently misrepresented a patient's medical conditions in order to prescribe more Subsys.

36. On or about August 11, 2014, Mr. Clough received a Notice of Hearing from the New Hampshire Board of Medicine alleging inappropriate prescribing practices. A few days after that notice, Mr. Clough allegedly communicated with Insys and informed them that he was no longer willing to participate in their Speaker Bureau. The State of New Hampshire brought a lawsuit against Insys in the Merrimack County Superior Court, alleging that the Insys speaker

programs conducted by Clough as a member of the Speaker Bureau were a scheme by Insys to provide payments to induce and in exchange for, prescribers to prescribe Subsys.

37. In March 2017, Clough was arrested by Federal authorities on charges of receiving financial kickbacks from Insys in exchange for prescribing Subsys.

38 In December 2018, Clough was found guilty in a Federal criminal trial on charges of Conspiracy and violations of a federal antikickback statute.

39. Ms. Langlois was oblivious to the development of criminal charges against Mr. Clough and Mr. Clough's involvement with Insys until November 26, 2018, when an FBI agent showed up at her door to give her a subpoena to testify at Clough's criminal trial. Ms. Langlois had no knowledge of Insys' influence on her prescription of Subsys or the fraudulent scheme of kickbacks orchestrated by Insys prior to that date. Ms. Langlois only has a basic cell phone, she does not have computer, watch the news, or read a newspaper.

40. Ms. Langlois previously received a phone call from a special agent with HHS-OIG who asked her about details of her Subsys prescription, whether she had signed TIRF-REMS paperwork, and details of her visits with Mr. Clough. This call took place on August 26, 2016, and Insys's fraudulent scheme and role in allegedly bribing Clough to prescribe Subsys were not discussed. Upon information and belief, no part of this phone call alerted Ms. Langlois to the Defendants causal relationship to the harm that she had suffered.

ROLE OF LINDEN CARE AND ROCHESTER DRUG CO-OPERATIVE IN INSYS' FRAUDULENT SCHEME

41. The Insys scheme to profit by marketing and promoting Subsys for non-approved off-label purposes would not have been possible without other actors willing to turn a blind eye to the volume and unlawful nature of Subsys prescriptions being written by providers who were part of the Insys Speakers program.

42. One such actor in the Insys Scheme was Linden Care, a New York pharmacy specializing in supplying opioids and pain medicine, who was ready to dispense large quantities of Subsys and look the other way. Linden Care turned a blind eye to clearly improper and unlawful prescription practices by providers including Clough and shipped Subsys to patients throughout the United States. Upon information and belief, Linden Care filled approximately 50% of the sales of Subsys in the United States and most, if not, all of the prescriptions written by Clough.

43. Linden Care was formed in New York in 2006 to provide concierge pharmacy services. It specialized in filling, dispensing, and shipping pain medications throughout the country via mail/commercial shipping services, most of which related to treatment of chronic disease and pain management. In essence, Linden Care was engaged in the practice of mail-order pharmacology, by and through its agents and employees, who were obligated to use professional skill, knowledge and care from their education, training, professional standards and by law.

44. As a dispenser of Subsys, Linden Care was subject to all the terms and conditions of the TIRF-REMS access program. Linden Care certified that it knew it could only fill Subsys prescriptions for patients with medical conditions warranting its prescription. In addition, Linden Care certified that it would comply with the dosage instructions: initial prescription at 100 mcg, with titration as necessary at the lowest possible increments. Linden Care knew that it could not dispense TIRF-REMS drugs to patients who were not enrolled in the TIRF-REMS program, and Linden Care knew under the Controlled Substance Act that it could not dispense controlled substances such as Fentanyl without physical possession of the original prescription.

45. At all times relevant to the Complaint, Linden Care ignored and subverted its legal duties by dispensing Subsys when it knew or should have known that Plaintiff, and patients like her, did not have cancer or other conditions that may have justified Subsys. Linden Care also

accepted and dispensed Subsys based only on facsimile prescriptions from Clough, and knowingly dispensed an initial dosage of 400 mcg to the Plaintiff and then filled additional prescriptions without proper titration practices. Upon information and belief, Insys also did not always verify that patients and their prescribing providers were enrolled in the TIRF-REMS program as required by law. Linden Care was careless and negligent in the manner in which it dispensed Subsys to the Plaintiff.

46. Linden Care filled and shipped the Plaintiff's prescription for the first time even after an initial phone call with the Plaintiff, where she told a Linden Care agent that she had never heard of the drug and had never discussed it with Clough. Furthermore, at the time that Linden Care filled Ms. Langlois's prescription her TIRF-REMS opt in paperwork had not even been generated. At this point Linden Care knew or should have known that the requirements of the TIRF-REMS program had not been met, and that filling the prescription would be negligent and unlawful.

47. Rochester Drug Co-operative also played a significant role in Insys' fraudulent scheme. RDC is a regional wholesale drug cooperative headquartered in Rochester, New York which supplied controlled substances to pharmacies including Linden Care at all times relevant to this complaint. RDC was one of the nation's top dispensers of Subsys and was the exclusive dispenser of Subsys to Linden Care.

48. As a distributor of controlled dangerous substances, RDC is required to operate a system to report to the DEA suspicious orders of controlled dangerous substances pursuant to 21 C.F.R. § 1301.74 (b).

49. Upon information and belief between May 2012 through November 2016 RDC received and filled over 1.5 million orders for controlled dangerous substances from its pharmacy customers, including Linden Care. Over this same period of time, RDC reported a

total of only four suspicious orders to the DEA, notwithstanding its legal obligation under the Controlled Substances Act. During this period of time RDC failed to report at least two thousand suspicious orders of controlled substances made by its pharmacy customers, specifically Linden Care.

50. At all times relevant to this Complaint, RDC, through their agents, servants and/or employees, negligently disregarded federal law concerning the sale of Subsys to Linden Care and acted to conceal the enormous volume of sales of Subsys and Linden Care's suspicious activities in regard to the drug, solely in the interests of profit.

51. On April 23, 2019, the CEO of RDC Laurence Doud was charged in the United States District Court for the Southern District of New York with conspiracy to traffic narcotics. The indictment in that case sets forth the specific allegations that Doud and RDC were knowingly dispensing drugs to individuals who had no legitimate need for them. Para. 16 of the indictment specifically identifies "Pharmacy 1" as one of the nation's largest dispensers of Subsys and indicates Doud and RDC intentionally and knowingly distributed huge amounts of Subsys to "Pharmacy 1" knowing they were being diverted for illegitimate purposes. Upon information and belief "Pharmacy 1" is Linden Care.

52. A three count criminal information charging RDC with conspiracy to distribute controlled substances outside the scope of professional practice and not for a legitimate medical purpose has been entered in the United States District Court for the Southern District of New York by consent decree.

53. RDC has entered into a Deferred Prosecution Agreement with the U.S. Department of Justice, accepting and acknowledging that RDC is guilty of and responsible for distributing controlled substances outside of professional practice and not for legitimate medical purposes.

COUNT I
NEGLIGENCE – LINDENCARE

54. The Plaintiff repeats and realleges each and every allegation in Paragraphs 1-49 above as though fully set forth herein.

55. Linden Care was bound by State and Federal laws which positioned them as a check and balance in the distribution of controlled substances and had a duty to abide by safety standards of care for their industry

56. The Defendant negligently violated the duties imposed upon it by its role in the county's pharmaceutical industry in the interest of greed when it failed to report suspicious activity in regard to Christopher Clough's prescription of the drug Subsys which it knew was being prescribed to patients without medical justification.

57. Linden Care was negligent by accepting faxed prescriptions for Subsys from Clough in violation of industry standards and the State and Federal Controlled Drug Acts.

58. Linden Care was negligent by filling prescriptions for Subsys when it had knowledge that the Plaintiff had not been counseled about the drug or enrolled in the TIRF-REMS program.

59. Linden Care was negligent for failing to verify that both providers prescribing Subsys, and the patients receiving the prescription were enrolled in the TIRF-REMS program as required by law.

60. Linden Care was negligent by filling an initial prescription of Subsys for the Plaintiff at a dose of 400 mcg, four times the initial dosage mandated by the TIRF-REMS program.

61. Linden Care was negligent by allowing the Plaintiff's prescriptions to be increased to dangerous levels far exceeding the 100 mcg titration guidelines set up by the TIRF-REMS program.

62. The Defendant knew the large volume of Subsys it was dispensing was going to individuals, such as the Plaintiff, that did not have a medical need for the drug and failed to meet the standard of care required of it as a distributor of controlled substances. The Defendant, as a pharmacy, knew that such prescriptions were dangerous and could lead to patient injury and death given the potent nature of Subsys.

63. As a direct and proximate result of the Defendant's negligent and unlawful conduct as described above, the plaintiff was caused to suffer great pain of body and mind, past, present and future and has undergone medical care and treatment and expended money for such care and treatment which is likely to continue in the future. The Plaintiff's ability to enjoy life has been adversely affected.

COUNT II
NEGLIGENCE – RDC

64. The Plaintiff repeats and realleges each and every allegation in Paragraphs 1-63 above as though fully set forth herein.

65. At all times relevant to this Complaint, RDC had a duty to follow industry standards of care along with State and Federal laws which positioned it as a check and balance in the distribution of controlled substances.

66. RDC negligently and unlawfully failed to report suspicious orders for large quantities of Subsys, a potent and dangerous drug only approved for patients with cancer pain, as it was required to under C.F.R. § 1301.74 (b).

67. RDC knew the large volume of Subsys it was selling was going to individuals that did not have a medical need for the drug and failed to meet the standard of care required of them as distributors of controlled substances. RDC knew that such prescriptions were dangerous and could lead to patient injury and death given the nature of Subsys.

68. As a direct and proximate result of the Defendant's conduct as described above, the plaintiff was caused to suffer great pain of body and mind, past, present and future and has undergone medical care and treatment and expended money for such care and treatment which is likely to continue in the future. The plaintiff's ability to enjoy life has been adversely affected.

WHEREFORE, the Plaintiff respectfully requests that this Honorable Court award judgment against the Defendants in accordance with an amount to be determined at a Jury Trial, together with attorney's fees, costs and interest.

Dated at Portsmouth, New Hampshire this 9th Day of July 2019.

Respectfully Submitted
Pamela Langlois

By her Attorneys,
COUGHLIN, RAINBOTH, MURPHY & LOWN

Dated: July 9, 2019

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